

46851-5

7/3/2014

1/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 3 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Lawrence E. Culleen,, Esq.
Arnold & Porter, LLP, Agent for
Centol International, LLC
555 Twelfth Street, NW
Washington, DC 20004-1206

Subject: Product Name: OMC-II Surface Disinfectant
EPA Registration No.: 46851-5
Notification Date: June 06, 2014
EPA Receipt Date: June 06, 2014

Dear Mr. Culleen,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 98-10.

Proposed Notification

- Updating to use the previously-approved signal words and warning statements.
- Adding indoor non-food use sites
- Adding non-pesticidal claims permitted by Section IV of PR Notice 98-10.

General Comments

Based on a review of the submitted materials, adding the previously approved signal words and warning statements, adding indoor non-food use sites and adding non-pesticidal claims permitted by Section IV of the PR Notice 98-10 are **acceptable** and apart of the record on file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Hardy", is written over the typed name.

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

A collection of 18 small, stylized line drawings of various birds, arranged in a grid-like fashion. The birds include songbirds, waterfowl, and raptors, each depicted in a simple, artistic style using only outlines and minimal shading.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other NOTIF

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 46851-5	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) OMC II Spray	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Certol International 6120 East 58th Avenue, Commerce City, CO 80022 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification per 98-10 to: a) return to use of previously-approved signal words; b) add indoor non-food use sites; and c) add non-pesticidal claims.

CONTINUED ON ADDITIONAL PAGE

Section - III

1. Material This Product Will Be Packaged In: NO CHANGES FROM PRIOR APPROVAL			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Lawrence E. Culleen	Title Counsel for Certol	Telephone No. (Include Area Code) 202.942.5477	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Data Application Received (Stamped)
2. Signature 	3. Title Counsel for Certol International		
4. Typed Name Lawrence E. Culleen	5. Date June 6, 2014		

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ARNOLD & PORTER LLP

Lawrence E. Culleen
Lawrence_Culleen@aporter.com

202.942.5477
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

June 6, 2014

VIA HAND DELIVERY

Document Processing Center
Office of Pesticide Programs/US EPA
2777 South Crystal Drive
Room S-4900
Arlington, VA 22202

Attention of: Jacqueline Campbell
Team Leader PM Team 34
Regulatory Management Branch II
Antimicrobials Division
Mail Code: 7510P

**Re: NOTIFICATION -- minor label revisions to label OMC II Spray
(EPA Reg. No. 46851-5)**

Dear Ms. Campbell:

On behalf of our client, Certol International, we are submitting the enclosed documents in support of this Notification seeking to make minor changes to Certol's currently-authorized label for its Omni-II disinfectant product (EPA Registration No. 46851-1). These minor modifications qualify for treatment as a Notification pursuant to PR Notice 98-10 because Certol is seeking only to:

- a) Harmonize the signal words and warning statements with previously-approved terms that inadvertently were not reflected on the most recently stamped label by the Agency on January 31, 2014 (the previously-authorized label that was stamped February 3, 2011 appears on PPLS and is included for reference). Because the signal words and warning statements have been based on previously-approved labels, no scientific review is required by EPA staff.
- b) List certain items found in hair salons and barbershops among the use sites and equipment that can be cleaned using the product. The language related to those use sites may be added by Notification pursuant to Section II.C. of PR Notice 98-10.

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Certol[®]
International

[Kills 99.9% of] [viruses*] [and] [bacteria**] [in 1 minute]]

ProSpray[™]

[Ready-to-Use] [Surface Disinfectant] [/] [Cleaner]

[One-Step[™]] [Cleaner] [/] [Disinfectant] [/] [Deodorizer]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against Section.]

[Tuberculocidal] [,] [Virucidal*] [,] [Bactericidal] [,] [Fungicidal]

[Kills Staphylococcus aureus - MRSA HA [in one minute]]

Active Ingredients

o-phenylphenol 0.28%

o-benzyl-p-chlorophenol 0.03%

Inert Ingredients 99.69%

Total 100.00%

E.P.A. Reg. No. 46851-5

E.P.A. Est. No. 46851-CO-003

[Lot #] [and] [expiration date] [printed on container]

Contents: [1 Gallon] [(3.79 liters)]

[Reorder No: _____]

NOTIFICATION
Date Reviewed: 7/3/14
Reviewed By: [Signature]

Keep Out of Reach of Children

CAUTION: Irritant

Do Not Take Internally

[See other panels for additional precautionary statements.]

[PRODUCT BARCODE:] [+H816 _____]

FIRST AID:

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

Statements in brackets, [], are optional or instructional. Sequence of statements is optional unless specified in 40 CFR 156.10. Capitalizing, pluralizing, singularizing, bolding, italicizing and abbreviation are variable unless specified in 40 CFR. Lists of uses and use sites may be used partially or in their entirety.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

In case of an emergency for additional information call toll free 1-800-535-5053. Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

PRECAUTIONARY STATEMENTS:

Hazardous to humans and domestic animals.

CAUTION: Harmful if swallowed, absorbed through skin or inhaled. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

USER SAFETY REQUIREMENTS: Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. [Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.]

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels are required. The last equipment/instrument/hard, non-porous surface listed will be preceded with the word "and".]

ProSpray™ is [a] [an] [effective] ["one-step"] [cleaner] [and] [broad-spectrum] [disinfectant] [according to the AOAC Use-Dilution Test] [,] [modified in the presence of 5% organic soil load] [and] [meets AOAC efficacy standards for hospital-use disinfectants.] [It cleans] [,] [disinfects] [and] [deodorizes] [hard non-porous surfaces] [in one labor-saving step].] [ProSpray™ may be used in [healthcare,] [office,] [transport,] [commercial] [and] [home settings] [on] [vinyl,] [plastics,] [metals,] [floors,] [walls,] [counters,] [carts] [and] [bedside equipment].]

[ProSpray™ is effective against the following microorganisms on hard non-porous surfaces when used as directed:]

[EFFECTIVE AGAINST:]

[MYCOBACTERIUM TUBERCULOSIS VAR. BOVIS [(TB)]]

[STAPHYLOCOCCUS AUREUS]**

[STAPHYLOCOCCUS AUREUS - MRSA HA]**

[SALMONELLA ENTERICA]**

[PSEUDOMONAS AERUGINOSA]**

[HIV-1 [(AIDS VIRUS)]*]

[HERPES SIMPLEX VIRUS TYPES 1 & 2*]

[TRICHOPHYTON MENTAGROPHYTES [(FUNGUS)]]

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DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[The following paragraph will be included in its entirety when the production label references healthcare use.]
 ProSpray™ is designed for use on hard non-porous surfaces and/or in holding solution. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

CLEANING: [ProSpray™ is an effective ready-to-use cleaning agent.] Apply ProSpray™ directly to surface using [spray] [bottle] [or] [mop]. Wipe surface to remove debris and solution using [clean] [paper] [or] [cloth] [towels] and discard. [Occasional [rinsing] [or] [wiping] [with] [damp] [cloth] is recommended when ProSpray™ is used frequently [on [floors,] [stainless steel,] [vinyl] [and] [other surfaces].]

[MEDICAL AND DENTAL INSTRUMENT HOLDING SOLUTION and ULTRASONIC INSTRUMENT CLEANING DEVICES: Fill [container] [or] [tank] [of ultrasonic cleaning device with fresh [ready-to-use] ProSpray™. [[Soak] [or] [operate device] [for 5 minutes.] Rinse articles thoroughly with potable water and pat dry. Package and sterilize instruments prior to use. The efficacy of the solution is compromised in the presence of organic matter. Use a fresh solution [daily] [or] [change] [more often] [if it becomes [diluted] [or] [soiled]. [For use on [metals] [,] [plastics] [,] [rubber] [and] [glass].]

[FOR CLEANING HAIR CLIPPERS AND ELECTRIC SHEARS: While [clipper] [/] [electric shear] is running, hold [clipper] [/] [electric shear] in downward position and spray ProSpray™ to thoroughly wet the blades. [Avoid spraying on the [clipper] [/] [electric shear] case or dripping into the [clipper] [/] [electric shear] housing.] Rinse [clipper] [/] [electric shears] and follow with [appropriate] [lubricating] [and] [disinfection] [process].]

[FOR CLEANING SALON IMPLEMENTS AND SHEARS: Spray ProSpray™ to thoroughly wet the [implement] [or] [shear]. [Wipe away visible debris using [a] [soft] [bristle] [brush] [or] [cloth]]. Rinse [implement] [or] [shear] and follow with [appropriate] [lubricating] [and] [disinfection] [process].]

DISINFECTION: Apply ready-to-use ProSpray™ to hard non-porous surfaces [such as floors,] [walls,] [counters] [and] [tables] [with [mop] [or] [spray] [using [clean] [paper] [or] [cloth] [towel]]]. All surfaces must remain wet for one minute. [Use a five minute contact time to inactivate TB.] Allow to air dry or remove excess with [clean] [mop] [,] [cloth] [or] [sponge]. For heavily soiled areas, a pre-cleaning step is required. [ProSpray™ may be used for this purpose.] [Use fresh solution [daily] [or] [change] [more often] [if it becomes [diluted] [or] [soiled when used [in [buckets,] [soak pans] [and] [ultrasonic] [instrument cleaning devices].] [[Wipe] [or] [rinse] surfaces periodically after disinfection.]

CONTACT TIME:

[ONE MINUTE EXPOSURE:]

[Staphylococcus aureus] [,] [Staphylococcus aureus - MRSA HA] [,] [Salmonella enterica] [,] [Pseudomonas aeruginosa] [,] [HIV-1] [(AIDS virus)] [,] [Herpes simplex virus types 1 & 2] [,] [Trichophyton mentagrophytes] [(Fungus)]

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[FIVE MINUTE EXPOSURE:]

[Mycobacterium tuberculosis var. bovis [(TB)]]

[FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES, INSTRUMENTS AND IMPLEMENTS: [Instruments must be thoroughly cleaned to remove excess organic debris [ProSpray™ may be used for this step], rinsed and dried. Apply ProSpray™ to pre-cleaned surfaces, thoroughly wetting areas to be disinfected. Allow surfaces to remain visibly wet for 5 minutes at room temperature [(68°F / 20°C)]. Rinse instruments and wipe dry prior to use.]]

[The following HIV instructions are to be included on production labels when claims against HIV are listed.]

ProSpray™ kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 HIV-1 [(associated with AIDS)].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear items such as disposable gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of ProSpray™. [ProSpray™ may be used for this purpose.]

CONTACT TIME: Allow surface to remain wet for one minute to kill [HIV-1 [(AIDS Virus)]], [Staphylococcus aureus] [,] [Staphylococcus aureus - MRSA HA] [,] [Salmonella enterica] [,] [Pseudomonas aeruginosa] [,] [Herpes simplex virus types 1 & 2] [and] [Trichophyton mentagrophytes [(Fungus)]]. [Use a five minute contact time for Mycobacterium tuberculosis var. bovis [(TB)].]

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in an area inaccessible to persons unfamiliar with its use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

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CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.

[Optional Marketing Claims:]

[Lemon Scent.]

[Fresh Scent.]

[AREAS OF USE:]

[NURSING, HOSPITAL AND HEALTHCARE SETTINGS:]

[[Ambulatory Surgical Centers]][(ASC)]]

[Anesthesia]

[Cat Labs]

[CCU]

[Central Supply Clinics]

[Clinics]

[Dental Offices]

[Dialysis]

[Doctors' Offices]

[Donation Centers [(Apheresis, Blood, Milk, Plasma, Semen)]]

[Emergency Medical Settings]

[Emergency Rooms]

[Endoscopy Centers]

[Eye Surgical Centers]

[GI Centers]

[Hospices]

[ICU]

[Isolation Areas]

[Laboratory]

[Laundry Rooms]

[[Operating Rooms]][(OR)]]

[Ophthalmic Offices]

[Orthopedics]

[[Out-patient Surgical Centers]][(OPSC)]]

[Patient Care Areas]

[Physical Therapy]

[Radiology]

[Reception Areas]

[Recovery Rooms]

[Rehabilitation]

[Respiratory Therapy]

[Surgery]

[Waiting Room]

[OFFICE AND HOME SETTINGS:]

[Libraries]

[Manufacturing Facilities]

[Office Buildings]

[Public Facilities]

[Schools]

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[OFFICE AND HOME SETTINGS (continued):]

- [Cabinets]
- [Computers]
- [Counters]
- [Desks]
- [Doorknobs]
- [Fax Machines]
- [Filing Cabinets]
- [Garbage Cans]
- [Hard Surfaces on Headsets]
- [Keyboards]
- [Public Telephones]
- [Railings]
- [Seats]
- [Sinks]
- [Tables]
- [Tabletops]
- [Telephones]
- [Work Stations]

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[EMERGENCY SERVICES SETTINGS:]

[Ambulances]
[Police Cars]
[Transport Vehicles]

[VETERINARY SETTINGS:]

[Isolation Areas]
[Veterinary Clinic]
[Waiting Room]

[HEALTH CLUB FACILITIES AND GYMS:]

- [Gym Equipment]
- [Locker Rooms]
- [Reception Areas]
- [Showers]

[SALONS, ESTHETICIANS, BARBER SHOPS:]

[Beauty Shops]
[Manicure Salons]
[Spas]
[Tattoo Parlors]

[BATHROOMS:]

- [Basins]
- [Bathroom Fixtures]
- [Bathtubs]
- [Cabinets]
- [Countertops]
- [Doorknobs]
- [Faucets]
- [Glazed Tiled Walls]
- [Hampers]
- [Handles]
- [Handrails]
- [Showers]
- [Sinks]
- [Toilet [(Handle, Rim, Seats, Tank, Other Exterior Surfaces)]]
- [Urinals [(Exterior Surface)]]

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[BATHROOMS (continued):]

cc [Vanity Tops]

[TRANSPORT SERVICE SETTINGS:]

cc [Fire Trucks]

cc [School Buses]

cc [Transport Vehicles]

cc [Hard Plastic or Metal Flooring]

cc [Seats]

cc [Steering Wheel]

cc [Walls]

[HARD NON-POROUS SURFACES:]

cc [Adapter Rings]

cc [Bed Frame]

cc [Bidet]

[Hard Surfaces on Booster Seats]

[Brass]

[Brushes]

[Chrome]

[Clean-up Carts]

[Clipper Blades]

[Combs]

[Copper]

[Crystal]

[Cuspidors]

[Dental Chairs]

[Dental Units]

[Digital X-Ray Sensors]

[Drains]

[Dressing Carts]

[Drinking Fountains]

[Electric Shears]

[Enamel]

[Examination Tables]

[Fixtures]

[Floors]

[Furniture [(Non Wood)]]

[Glass]

[Glazed Ceramic Tile]

[Glazed Porcelain Tile]

[Grocery Cart Handles]

[Grocery Cart Child Seats]

[Hair Care Implements]

[Hair Clippers]

[Laminate]

[Lamps]

[Light Switches]

[Linen Carts]

[Linoleum]

[Litter Boxes]

[Manicure Implements]

[Manicure Tables]

[Marble [(Culture, Synthetic)]]

[Marlite]

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[HARD NON-POROUS USE SITES (continued):]

- c c [Studio]
- c c c [Sut room]
- c [Tool Shed]
- c [Workshop]

[HARD NON-POROUS PROFESSIONAL USE SITES:]

- c c [Barber Shops]
- c c c [Beauty Shops]
- c c c [Blood Bank]
- c [Clinic]
- c c [College]
- c c [Commercial Building]
- c c c [Correctional Facilities]
- c c c [Dental Office]
- [Doctors' Office]
- [Grocery Store]
- [Gymnasium]
- [Health Care Facility]
- [Health Club]
- [Hospital]
- [Hotel][:][Motel]
- [Kennel]
- [Laboratory]
- [Laundromat]
- [Libraries]
- [Manicure Salons]
- [Manufacturing Facilities]
- [Military Installation]
- [Morgues]
- [Mortuaries]
- [Nursing Home]
- [Office Building]
- [Patient Room]
- [Pharmacy]
- [Public Places]
- [Recreational Center]
- [Restroom]
- [Salon]
- [Schools]
- [Shelter]
- [Sick Room]
- [Spas]
- [Tattoo Parlors]
- [Veterinary]
- [Warehouse Club]

[ProSpray is recommended for use in healthcare settings.]

[ProSpray is intended for use [on] [/] [in] medical [devices] [/] [settings].]

[ProSpray is a multi-purpose [disinfectant][/][decontaminant] [cleaner] for use on hard non-porous inanimate surfaces.]

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[ProSpray will effectively clean and disinfect, when used as directed, such items as [list]]

[Non-critical medical devices are items that come in contact only with intact skin.]

[ProSpray is an effective method to clean against odor-causing organisms on hard non-porous surfaces listed on this label.]

[Non-alcohol actives]

[Indicated for use when manufacturer's instructions recommend avoiding alcohol [on] [vinyls] [or] [plastics].]

[No bleach actives]

[Water-based intermediate-level disinfectant]

[Broad based material compatibility]

[The following statement is to be included on production labels when food contact areas or surfaces are listed:]

[A thorough rinse with potable water is required for surfaces in direct contact with food.]

Certol®
International

A Limited Liability Company

6120 East 58th Avenue
Commerce City, CO 80022 USA
Toll-free: (800) 843-3343
www.certol.com

[PSC/EPA/TX05 05/14]

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